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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/580,480

02/14/2008

Thomas A. Miller

21825P

4338

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7590

07/08/2010

MERCK

P O BOX 2000

RAHWAY, NJ 07065-0907

EXAMINER

OH, TAYLOR V

ART UNIT

PAPER NUMBER

1625

MAIL DATE

DELIVERY MODE

07/08/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/580,480	Applicant(s) MILLER ET AL.	
	Examiner Taylor Victor Oh	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14,21,22,25,26,34 and 35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-14,21,22,25,26,34 and 35 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

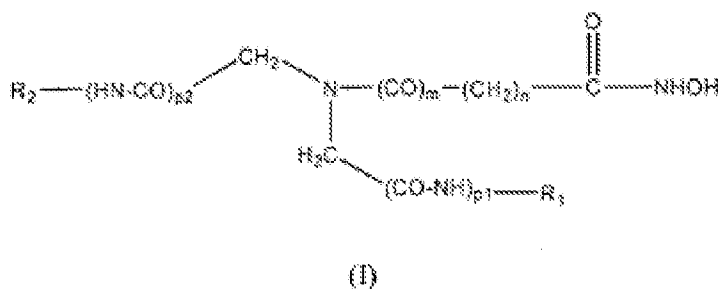
LACK OF UNITY

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-14,21-22, drawn to a non-heterocyclic or heteroaromatic compound of formula(I) and its pharmaceutical composition:



wherein

n is 2, 3, 4, 5, 6, 7 or 8;

m is 0 or 1;

p₁ and p₂ are independently of each other 0 or 1;

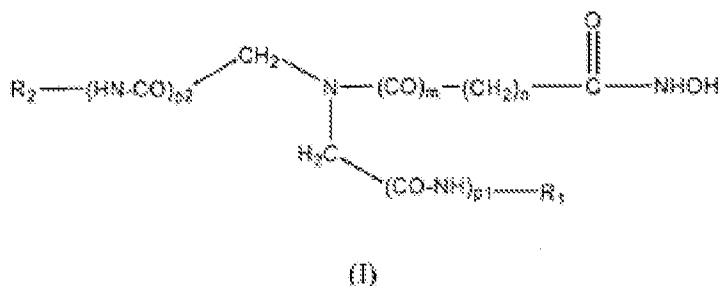
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R_1 and R_2 are independently of each other an unsubstituted or substituted aryl, cycloalkyl, alkylaryl, alkylcycloalkyl or when at least one of p_1 or p_2 is not

0, R_1 or R_2 or both can also represent hydrogen or alkyl;

and pharmaceutically acceptable salts, solvates, hydrates, prodrugs and polymorphs thereof.

Group II, claims 1-14, 21-22 drawn to a heterocyclic compound or heteroaromatic compound of formula(I) and its pharmaceutical composition:



wherein

n is 2, 3, 4, 5, 6, 7 or 8;

m is 0 or 1;

p_1 and p_2 are independently of each other 0 or 1;

R_1 and R_2 are independently of each other

heteroaryl, heterocyclyl, alkylheteroaryl, alkylheterocyclyl; or when p_1 and p_2 are both 0, R_1 and R_2 together with the $-CH_2-N-CH_2-$ group to which they are attached can also represent a nitrogen-containing heterocyclic ring;

and pharmaceutically acceptable salts, solvates, hydrates, prodrugs and polymorphs thereof.

Group III, claims 25-26 and 34-35, drawn to a method for treating cancer or tumor in a subject by administering the compound of the formula (I).

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (" requirement of unity of invention ").

PCT Rule 13.2 states " Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression " special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

In the instant case , the invention of Group I is directed to the non-heterocyclic or non-heteroaromatic compound of formula (I) and its pharmaceutical composition, whereas the invention of Group II is directed to the heterocyclic or heteroaromatic compound of formula (I) and its pharmaceutical composition. They have two distinct

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chemical structures and different functional groups attached to the back bone of formula(I) ;for example, to the heterocyclic compound of the invention of Group II, the various heterocyclic or heteroaromatic groups such as pyridyl , morpholinyl or benzothiazolyl group and etc. is attached ; the presence of such different functional groups exhibits a chemically different activity during the reaction. Therefore, there is no special technical feature of Group I required in Group II. There is no single general inventive concept and no unity of invention for the method or the processes as defined in 37 CFR 1.475.

In the instant case, the invention of Group I is directed to the non-heterocyclic or non-heteroaromatic compound of formula (I) and its pharmaceutical composition, whereas the invention of Group III is directed to the method for treating cancer or tumor in a subject by administering the compound of the formula (I).

According to Ekwuribe et al (US 7,119,074), the reference discloses the method for the treatment of cancer or tumor by using a therapeutic compound conjugated to PEG-oligomer/polymer. From this, the Group III can be practiced without the requirement of the compound of the formula (I) from group I , which is the common link between the Group III and the Group I. Therefore, the Group III is not required for the invention of Group I ; there is no special technical feature between Group III and Group I.

Therefore, there is no single general inventive concept and no unity of invention for the method or the process as defined in 37 CFR 1.475.

37 CFR 1.475 states that a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combination of categories:

- a. A product and a process specially adapted for the manufacture of said product;
or
- b. A product and a process of use of said product; or
- c. A product, a process specially adapted for the manufacture of the said product,
and a use of the said product; or
- d. A process and an apparatus or means specially designed for carrying out the
said process; or
- e. A product, a process specially adapted for the manufacture of the said product,
and an apparatus or means specially designed for carrying out the said process.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Taylor Victor Oh/
Primary Examiner, Art Unit 1625
7/06/10